

***Remarks***

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendments, claims 1-3, 13-33, and 36 are pending in the application. Claims 4-12, 34, and 35 are being canceled without prejudice to or disclaimer of the subject matter therein. Claims 1, 15, 17, 24, 30-33, and 36 have been amended. Support for the amendment to claim 1 can be found in the specification at, *e.g.*, page 25, line 27, to page 26, line 4, and original claim 1. Support for the amendment to claims 15, 24, and 32 is provided by the provisions of 37 C.F.R. §§1.809(d) and (e) and page 17 of the specification, as amended on November 19, 2003. Support for the amendments to claims 17, 33, and 36 can be found in original claims 17, 33, and 36, respectively. Support for the amendment to claims 30 and 31 can be found in the specification at, *e.g.*, page 16, line 14, to page 17, line 5. There is no issue of new matter.

It is believed that the amendments to the claims will put the case in condition for allowance.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider the objections and rejections and that they be withdrawn.

***Summary of the Invention***

The claims are directed to cell-specific and/or tumor-specific herpes viral mutants (and methods utilizing said mutants) comprising, at a minimum, a mutation in the gene encoding  $\gamma$ 34. 5 and an insertion of at least one copy of the  $\gamma$ 34. 5 gene under the transcriptional control of a cell specific and/or tumor specific promoter.

***Applicants' Statement of Substance of Telephonic Interview***

Applicants thank Examiner Woitach for the courtesy extended to their undersigned representative in a telephonic interview on July 14, 2004.

The Examiner Interview Summary (which includes an attached Continuation Sheet), mailed July 20, 2004, accurately reflects the substance of the interview, however, in accordance with 37 C.F.R. §1.133(b) and MPEP §713.04, Applicants' undersigned representative provides the following statement of the substance of the interview.

Applicants contacted Examiner to request consideration of proposed claim amendments to address the rejections of record. The Examiner reviewed a fax copy of the amendments and proposed several changes. Specifically, in claim 1, the Examiner proposed that 'targeting' in the last line be changed to 'targeted expression.' In claims 17 and 33, the Examiner proposed changing 'the promoter' to 'a promoter' in step b), and inserting 'expressing a tumor-specific protein' (in claim 17) and 'expressing a cell-specific protein' (in claim 33) in the first method step to give proper antecedent basis for 'said tumor-specific protein' (claim 17) and 'cell-specific protein' (claim 33) in step b). In claims 15, 24, and 32, the Examiner proposed amending the claims to encompass a Myb34.5 as represented by the ATCC deposit. Applicants pointed out to the Examiner that page 2 of the Office Action mistakenly stated that claim "30" should be amended to include the ATCC accession number, and that it was presumed that claim "32" was intended. The Examiner acknowledged the error. During the interview, the Examiner noted that while the deposit was properly made, it was not signed by someone of record or power of attorney in the case and that a declaration signed by the inventor or attorney would have to be filed to satisfy the deposit requirements.

Applicants respectfully request that the substance of the interview be recorded.

***Objections***

At page 2, last paragraph, of the current Office Action, the Examiner objected to claims "15, 24 and 30" [sic:32] for not reciting the specific patent deposit designation number assigned to Myb34.5 (*i.e.*, PTA-4963). Claims 15, 24, and 32 (*not claim 30*) have been amended in accordance with the Examiner's suggestion during the telephone interview of July 14, 2004. Withdrawal of this objection is respectfully requested.

Further in this regard, at the request of Examiner Woitach during the telephonic interview on July 14, 2004, Applicants provide the following statement concerning the deposited viral mutant, Myb34.5: Herpes Simplex Virus Type 1 Myb 34.5 was deposited under the terms of the Budapest Treaty on or around January 28, 2003<sup>1</sup>. The deposit was made at the American Type Culture Collection (ATCC), located at 10801 University Boulevard, Manassas, Virginia 20110-2209, and was given patent deposit designation PTA-4963. Assurance is hereby given that all restrictions on the availability to the public of the deposit will be irrevocably removed upon the granting of a patent, subject to 37 C.F.R. §1.808(b).

***Rejections Under 35 U.S.C. § 112, first paragraph (written description and enablement)***

At pages 3-5 of the current Office Action, the Examiner rejects claims 1-3, 13-33 and 36 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. More specifically, the Examiner contends that the prior amendment

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<sup>1</sup> According to the deposit receipt, which was filed in the USPTO as Exhibit A on November 19, 2003, the deposit was *received* by the ATCC on January 28, 2003.

to claim 1 resulted in a change from "two elements [of] inactivated  $\gamma$ 34.5 and an inserted copy of  $\gamma$ 34.5" to "a vector wherein it appears that a transcriptional control is operatively linked to [the] mutated  $\gamma$ 34.5 gene." According to the Examiner, "the claims have been amended to delete the recitation that the 'at least one copy of the  $\gamma$ 34.5 gene" is "an insertion" and the claim now reads on inserting a promoter in front of the deleted or inactivated copy of the gene encoding  $\gamma$ 34.5 which is not recited nor generally defined in the instant specification."

While Applicants respectfully traverse this rejection, solely to expedite allowance, Applicants have amended the claims in accordance with the Examiner's suggestions. It is believed that this rejection has been overcome and should be withdrawn.

At page 4, first full paragraph, of the current Office Action, the Examiner also rejects the claims for lack of enablement under 35 U.S.C. §112, first paragraph, "since a disclosure cannot teach one to make or use something that has not been described." In view of the amendments to the claims, it is believed that this rejection has also been overcome and should be withdrawn.

***Rejection Under 35 U.S.C. §112, second paragraph***

At page 5, last paragraph, of the current Office Action, the Examiner rejects claims 1-3, 13-33 and 36 under 35 U.S.C. §112, second paragraph, for indefiniteness because "it is unclear how operatively linking one of the deleted or inactivated copies of the  $\gamma$ 34.5 to a cell-specific and/or tumor-specific promoter will allow for specific targeting. Without a functional copy of the  $\gamma$  34.5 the viral mutant will not be selective."

In view of the amendments to the claims, it is believed that this rejection has also been overcome and should be withdrawn.

***Objection to the Specification***

At page 6, first paragraph, of the current Office Action, the Examiner objects to the specification as failing to provide antecedent basis for the claimed subject matter. More specifically, the Examiner states that the prior amendment deleted the recitation that the "at least one copy of the  $\gamma$ 34.5 gene" is "an insertion" such that the claim now reads on inserting a promoter in front of the deleted or inactivated copy of the gene encoding  $\gamma$ 34.5 which is not recited nor generally defined in the specification.

In view of the amendments to the claims, it is believed that this objection to the specification has also been overcome and should be withdrawn.

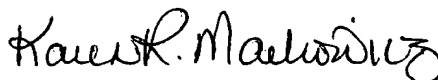
### ***Conclusion***

All of the remaining grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all currently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned directly at (202) 772-8637.

Prompt and favorable consideration of this Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Karen R. Markowicz  
Agent for Applicants  
Registration No. 36,351

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1100 New York Avenue, N.W.  
Washington, D.C. 20005-3934  
(202) 371-2600